

**AGRI-MECTIN - ivermectin liquid**  
**Agri laboratories Ltd.**

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**AGRI-MECTIN (ivermectin) Pour-On for Cattle**

ANADA 200-299, Approved by the FDA

**Contains 5 mg ivermectin/mL**

**Parasiticide**

**Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.**

**INTRODUCTION**

Ivermectin Pour-On delivers internal and external parasite control in one convenient low-volume application. Ivermectin Pour-On contains ivermectin, a unique chemical entity.

**MODE OF ACTION**

Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).

The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

**INDICATIONS**

Ivermectin Pour-On applied at the recommended dose level of 500 mcg/kg is indicated for the effective treatment and control of these parasites:

**Gastrointestinal Roundworms**

<i>Ostertagia ostertagi</i> (including inhibited stage)	(adults and L <sub>4</sub> )
<i>Haemonchus placei</i>	(adults and L <sub>4</sub> )
<i>Trichostrongylus axei</i>	(adults and L <sub>4</sub> )
<i>T. colubriformis</i>	(adults and L <sub>4</sub> )
<i>Cooperia oncophora</i>	(adults and L <sub>4</sub> )
<i>Cooperia punctata</i>	(adults and L <sub>4</sub> )
<i>Cooperia surnabada</i>	(adults and L <sub>4</sub> )
<i>Strongyloides papillosus</i>	(adults)
<i>Oesophagostomum radiatum</i>	(adults and L <sub>4</sub> )
<i>Trichuris</i> spp.	(adults)

<b>Lungworms</b>	<i>Dictyocaulus viviparus</i>	(adults and L <sub>4</sub> )
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<b>Cattle Grubs</b>	<i>Hypoderma bovis</i> , <i>H. lineatum</i>	(parasitic stages)
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<b>Mites</b>	<i>Sarcoptes scabiei</i> var. <i>bovis</i>
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<b>Lice</b>	<i>Linognathus vituli</i> , <i>Haematopinus eurysternus</i> , <i>Damalinea bovis</i> , <i>Solenopotes capillatus</i>
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<b>Horn Flies</b>	<i>Haematobia irritans</i>
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**Persistent Activity**

Ivermectin Pour-On has been proved to effectively control infections and to protect cattle from re-infection with: *Oesophagostomum radiatum* and *Dictyocaulus viviparus* for 28 days after treatment; *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment; *Ostertagia ostertagi*,

*Haemonchus placei*, *Cooperia oncophora* and *Cooperia surnabada* for 14 days after treatment; *Damalinia bovis* for 56 days after treatment.

### **Treatment of Cattle for Horn Flies**

Ivermectin Pour-On controls horn flies (*Haematobia irritans*) for up to 28 days after dosing. For best results Ivermectin Pour-On should be part of a parasite control program for both internal and external parasites based on the epidemiology of these parasites. Consult your veterinarian or an entomologist for the most effective timing of applications.

### **DOSAGE**

The dose rate is 1 mL for each 22 lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

### **ADMINISTRATION**

#### **Squeeze-Measure-Pour System**

##### **(8.5 fl. oz/250 mL Bottle with 25 mL Measuring Cup)**

Measure the amount of solution to be used, at the dose of 1 mL for each 22 lb of body weight into a measuring cup. When body weight is between markings use the higher setting.

Tilt the measuring cup to deliver the dose.

#### **Squeeze-Measure-Pour System**

##### **(33.8 fl. oz/1 L Bottle with 25 mL Measuring Cup)**

Measure the amount of solution to be used, at the dose of 1 mL for each 22 lb of body weight into a measuring cup. When body weight is between markings use the higher setting.

Tilt the measuring cup to deliver the dose.

#### **Collapsible Packs**

##### **(84.5 fl. oz/2.5 L Pack and 169 fl. oz/5 L Pack)**

Connect the applicator gun to the collapsible pack as follows: Attach the open end of the draw-off tubing to dosing equipment. Replace the shipping cap with the draw-off cap and tighten down. Attach draw-off tubing to the draw-off cap.

Gently prime the applicator gun, checking for leaks.

Follow the manufacturer's directions for adjusting the dose.

When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun and draw-off tubing from the product container and empty the product from the gun and tubing back into the product container. To prevent removal of special lubricants from the applicator gun, the gun and tubing must not be washed.

### **ANIMAL SAFETY**

Studies conducted in the U.S.A. have demonstrated the safety margin for ivermectin. Based on plasma levels, the topically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

### **WARNING! DO NOT USE IN HUMANS.**

#### **Keep this and all drugs out of the reach of children.**

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact Med-Pharmex, Inc. at (909) 593-7875.

### **WARNING! FLAMMABLE!**

#### **KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF**

## IGNITION.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

**RESIDUE INFORMATION:** Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, **do not use** in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. **Do not use** in calves to be processed for veal.

## PRECAUTIONS

**Store away from excessive heat (104°F/40°C) and protect from light.**

- Use only in well-ventilated areas or outdoors.
- Close container tightly when not in use.
- Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.
- Do not use when rain is expected to wet cattle within six hours after treatment.
- This product is for application to skin surface only. Do not give orally or parenterally.
- Cloudiness in the formulation may occur when Ivermectin Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.
- Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange, scabs or lesions, or with dermatoses or adherent materials, e.g., caked mud or manure.
- Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, Ivermectin Pour-On is not recommended for use in species other than cattle.

## When to Treat Cattle with Grubs

Ivermectin Pour-On effectively controls all stages of cattle grubs. However, proper timing of treatment is important. For the most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble fly) season. While this is not peculiar to ivermectin, destruction of *Hypoderma* larvae (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions. Killing *Hypoderma lineatum* when it is in the esophageal tissues may cause bloat; killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. Cattle should be treated either before or after these stages of grub development. Cattle treated with Ivermectin Pour-On at the end of the fly season may be re-treated with Ivermectin during the winter without danger of grub-related reactions. For further information and advice on a planned parasite control program, consult your veterinarian.

## Environmental Safety

Studies indicate that when ivermectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish or certain water-borne organisms on which they feed. Do not permit cattle to enter lakes, streams or ponds for at least six hours after treatment. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

As with other avermectins, ivermectin is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependent insects.

## HOW SUPPLIED

Ivermectin Pour-On is available in an 8.5 fl. oz/250 mL bottle or 33.8 fl. oz/1 L bottle with a squeeze-measure-pour system, or in an 84.5 fl. oz/2.5 L or 169 oz/5 L collapsible pack container intended for use with appropriate automatic dosing equipment.

**Indications:** For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

**Recommended Dose:**  
1 mL per 22 lb of body weight.

**RESIDUE INFORMATION:** Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

Keep this and all drugs out of the reach of children.

## AGRI-MECTIN® (ivermectin)



Contains 10 – 550 lb Doses

### POUR-ON FOR CATTLE

Contains: 5 mg Ivermectin/mL

#### INTERNAL and EXTERNAL PARASITICIDE for CATTLE

**Kills:** Roundworms (including Brown Stomach Worm),  
Lungworms, Grubs, Sucking Lice, Biting Lice,  
Mange Mites, Horn Flies

**WARNING: Flammable!**

Keep Away from Heat, Sparks, Open Flame,  
and Other Sources of Ignition.

**WARNING: Not for Use in Humans.**

Consult your veterinarian for assistance in the  
diagnosis, treatment and control of parasitism.



Mfd. for Agri Laboratories, Ltd., St. Joseph, MO 64503  
ANADA # 200-299, Approved by FDA

Net Contents: 8.5 fl oz (250 mL)

#### PRECAUTIONS:

**Store away from excessive heat (104°F/40°C) and protect contents from light.**

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when AGRI-MECTIN® is stored at temperatures below 32° F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g. caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, AGRI-MECTIN® is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers.

Dispose of containers in an appropriate landfill or by incineration.

Lot # / Exp. Date

**Indications:** For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

**Recommended Dose:**  
1 mL per 22 lb of body weight.

**RESIDUE INFORMATION:** Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

Keep this and all drugs out of the reach of children.

## AGRI-MECTIN® (ivermectin)



Contains 40 – 550 lb Doses

### POUR-ON FOR CATTLE

Contains: 5 mg Ivermectin/mL

#### INTERNAL and EXTERNAL PARASITICIDE for CATTLE

**Kills:** Roundworms (including Brown Stomach Worm),  
Lungworms, Grubs, Sucking Lice, Biting Lice,  
Mange Mites, Horn Flies

**WARNING: Flammable!**

Keep Away from Heat, Sparks, Open Flame,  
and Other Sources of Ignition.

**WARNING: Not for Use in Humans.**

Consult your veterinarian for assistance in the  
diagnosis, treatment and control of parasitism.



Mfd. for Agri Laboratories, Ltd., St. Joseph, MO 64503  
ANADA # 200-299, Approved by FDA

Net Contents: 33.8 fl oz (1 Liter)

#### PRECAUTIONS:

**Store away from excessive heat (104°F/40°C) and protect contents from light.**

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when AGRI-MECTIN® is stored at temperatures below 32° F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g. caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, AGRI-MECTIN® is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers.

Dispose of containers in an appropriate landfill or by incineration.

Lot # / Exp. Date

## AGRI-MECTIN

ivermectin pour-on liquid

### Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:57561-019	
Route of Administration	TOPICAL	DEA Schedule		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
IVERMECTIN (UNII: 8883YP2R6D) (IVERMECTIN - UNII:8883YP2R6D)		IVERMECTIN	5 mg in 1 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57561-019-87	250 mL in 1 BOTTLE, PLASTIC		
2	NDC:57561-019-88	1000 mL in 1 BOTTLE, PLASTIC		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANADA	ANADA200299	12/01/2006		

**Labeler** - Agri laboratories Ltd. (155594450)

**Registrant** - Med-Pharmex, Inc (025353699)

Establishment			
Name	Address	ID/FEI	Business Operations
Med-Pharmex, Inc		025353699	manufacture